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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,896	06/11/2001	J. Antoni Rafalski	BB-1313	2782

23906 7590 03/23/2004

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EXAMINER

BUI, PHUONG T

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/857,896

Applicant(s)

RAFALSKI ET AL.

Examiner

Phuong T. Bui

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 2/6/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 24,26-28,31-35 and 37-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24,26-28,31-35 and 37-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***DETAILED ACTION***

1. Applicant's Request for Continued Examination (RCE) filed February 6, 2004 has been received. The amendment of December 22, 2003 has been entered. Claims 24, 26-28, 31-35 and 37-40 are pending and are examined in the instant application.

***Claim Rejections - 35 USC § 112***

2. Claims 24, 26-28, 31-35 and 37-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Applicant is invited to point to the page and line number in the specification where support can be found for the recitation of "fungal disease resistance activity when expressed in a plant". Page 2, lines 5-19 does not provide support for said recitation as alleged by Applicant. Absent of such support, Applicant is required to cancel the new matter in response to the instant Office action.

3. Claims 24, 26, 31-35 and 37-40 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description requirement based on the less than 100% sequence identity language in the claims.

Art Unit: 1638

The 90-95% sequence identity language lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass Mlo proteins from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:32 isolated from *Triticum aestivum*. Thus, there is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and Mlo proteins from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

4. Claims 24, 26-27, 31-35 and 37-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:31, does not reasonably provide enablement for SEQ ID NO:32 and sequences reciting 90-95% sequence identity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claims reciting 90-95% sequence identity are not enabled because they encompass unspecified base deletions, additions, substitutions, and combinations thereof while retaining the asserted activity. Applicant

provided no working examples or further guidance as to which region(s) of SEQ ID NO:31 or SEQ ID NO:32 are conserved domains necessary for protein activity. While skilled in the art can readily make base changes, further guidance is necessary as to what changes would be tolerated. Absent of such guidance, it is highly unpredictable as to which sequences encompassed by the claims would have the asserted activity. SEQ ID NO:32 is not enabled because the nucleotide sequences encoding SEQ ID NO:32 are degenerate DNAs. While degenerate DNAs can be used to express SEQ ID NO:32, the only use set forth in the specification for the claimed polynucleotide is sense or antisense inhibition or targeted gene disruption of Mlo, which would require SEQ ID NO:31 and not degenerate DNAs encoding SEQ ID NO:32. Degenerate DNAs would not bind to the targeted gene and thus would not inhibit or disruption the Mlo gene (see also the 101 rejection in the previous Office rejection of October 22, 2003). Accordingly, one skilled in the art cannot make and use the claimed invention as commensurate in scope with the claims without undue experimentation.

5. No claim is allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phuong T. Bui  
Primary Examiner  
Art Unit 1638

3/20/04